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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/484,048	01/18/00	STEEN	S 33314WC54893

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EXAMINER

SAUCIER, S

ART-UNIT	PAPER NUMBER
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1651

DATE MAILED:

08/13/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/484,048

Applicant(s)

Steen

Examiner
Sandra Saucier

Art Unit
1651



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on Jun 8, 2001

2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1035 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1-32 is/are pending in the application.

4a) Of the above, claim(s) 2-4 and 8-23 is/are withdrawn from consideration.

5) ☒ Claim(s) 5, 7, and 24-32 is/are allowed.

6) ☒ Claim(s) 1 and 6 is/are rejected.

7) ☐ Claim(s) is/are objected to.

8) ☐ Claims are subject to restriction and/or election requirements.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☒ All b) ☐ Some* c) ☐ None of:

- ☐ Certified copies of the priority documents have been received.
- ☒ Certified copies of the priority documents have been received in Application No. 09/093,614.
- ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s).
- 18) ☐ Interview Summary (PTO-413) Paper No(s).
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

Art Unit: 1651

DETAILED ACTION

Claims 1-32 are pending. Claims 1, 5-7, 24-32 are considered on the merits. Claims 2-4, 8-23 are withdrawn from consideration as being drawn to a non-elected invention.

Please cancel the non-elected claims, 2-4, 8-23 in the next response in order to put the application more swiftly in condition for allowance.

Priority

Acknowledgment is made of applicant's claim for priority under 35 U.S.C. 119(a)-(d) based upon an application filed in Sweden on 12/15/95. A claim for priority under 35 U.S.C. 119(a)-(d) cannot be based on said application, since the parent United States application, 09/093614 was filed more than twelve months thereafter.

Please note that the oath/declaration submitted 4/20/2000 has the wrong title of invention, and does not claim priority to PCT/SE96/01664. Also, an amendment has been made to the oath without dating and initialing (See citizenship). A new oath/declaration is suggested if applicant wishes to be entitled to his Swedish application date of priority.

Contrary to applicant's statement, no new oath has been entered into the pending application, thus applicant's priority claim has not been perfected.

Claim Rejections - 35 USC § 103

Claims 1 and 6 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Ingemansson *et al.* [AV] and Pinsky *et al.* [AQ] or Naka *et al.* [AT].

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The claims, with their narrowest limitations, are directed to a composition comprising

Ca⁺⁺,
5% dextran 40KDa,
5mM dextrose,
6mM K⁺
0.8mM Mg⁺⁺
138 mM Na⁺,
142 mM Cl⁻,

Art Unit: 1651

0.8mM sulfate anion
0.24mM THAM,
0.8mM phosphate anion,
nitroglycerin.

The references are relied upon as explained below.

Ingemansson *et al.* disclose a commercial composition, Perfadex plus Ca^{++} , used to preserve vasculature comprising
1.5mM Ca^{++} ,
5% dextran 40,
5mM dextrose,
6mM K^{+} ,
0.8 mM Mg^{++}
138 mM Na^{+} ,
142 mM Cl^{-} ,
0.24mM THAM
0.8mM phosphate anion

This composition is lacking the inclusion of nitroglycerin.

Pinsky *et al.* or Naka *et al.* disclose that nitroglycerin maintains vascular homeostasis. It is added to known perfusion and preservative solutions such as lactated Ringer's in an amount of $0.01-0.1 \text{ mg/ml} = 5-50 \mu\text{M}$.

The addition of nitroglycerin to the solution of Ingemansson *et al.* would have been obvious when taken with Pinsky *et al.* or Naka *et al.* which teach the addition of nitroglycerin to maintain vascular homeostasis to preservative solutions.

Claims 1 and 6 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Ingemansson *et al.* [AT] and Nozick *et al.* [AU] Pinsky *et al.* [AQ] or Naka *et al.* [AT].

Ingemansson *et al.* disclose a commercial composition, Perfadex, used to preserve vasculature comprising:
5% dextran 40,
5mM dextrose,

Art Unit: 1651

6mM K⁺,
0.8 mM Mg⁺⁺
138 mM Na⁺,
142 mM Cl⁻,
0.24mM THAM
0.8mM phosphate anion

This composition is lacking the inclusion of Ca⁺⁺ and nitroglycerin.

Nozick *et al.* disclose that solutions used to irrigate vascular grafts should contain Ca⁺⁺ in order to avoid damage to the graft.

The inclusion of Ca⁺⁺ to the solution disclosed by Ingemansson would have been obvious when taken with Nozick *et al.* who teach that the presence of calcium ion in solutions is critical to the maintaining of vascular grafts prior to transplantation.

Pinsky *et al.* or Naka *et al.* disclose that nitroglycerin maintains vascular homeostasis. It is added to known perfusion and preservative solutions such as lactated Ringer's or University of Wisconsin Solution in an amount of 0.01 – 0.1mg/ml = 5–50µM (see abstract).

One of skill in the art would have been motivated at the time of invention to make these additions in order to obtain the resulting composition as suggested by the references with a reasonable expectation of success. The claimed subject matter fails to patentably distinguish over the state of the art as represented by the cited references. Therefore, the claims are properly rejected under 35 U.S.C. § 103.

Allowable Subject Matter

Claims 5, 7 and 24–32 are allowable.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is

Art Unit: 1651

filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1651. The supervisor for 1651 is M. Wityshyn, (703) 308-4743.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Saucier whose telephone number is (703) 308-1084. Status inquiries must be directed to the Service Desk at (703) 308-0196. The number of the Fax Center for the faxing of papers is (703) 308-4227.

A handwritten signature in black ink, appearing to read 'Sandra Saucier', with a stylized flourish at the end.

Sandra Saucier
Primary Examiner
Art Unit 1651
August 10, 2001